



Agencia de Calidad Sanitaria de Andalucía
CONSEJERÍA DE SALUD



ACSA
International



Funded by
the Health Programme
of the European Union

Andalusian Agency for Healthcare Quality Independent Assessment Body

Network Assessment Report

EURACAN

This report has been developed in the framework of the service contract signed between ACSA as contractor and Chafea as contracting authority. The opinions expressed in this document are those of the contractor only and do not represent European Commission or Consumers, Health, Agriculture and Food Executive Agency official position.

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Confidentiality Statement

The results of the assessment of EURACAN are documented in the attached report which was prepared by the Independent Assessment Body.

This report is based on information obtained from the Network and Healthcare Providers through the application forms, self-assessments, supporting documentation and the on-site audit. The Independent Assessment Body relies on the accuracy of this information to prepare the report.

This confidential report is intended for the Network and Healthcare Providers, the European Commission, and the Board of Member States. Any alteration of this report is strictly prohibited.

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1. Introduction

The assessment model for the European Reference Networks (ERNs) is a voluntary process that fosters a culture of quality improvement and offers a peer review assessment of highly specialised healthcare providers. The assessment process provides a standardised method for forming and evaluating ERNs under the regulatory framework of the Commission Delegated and Implementing Decisions of 10 March 2014. It has a stepwise approach that may include a comprehensive assessment of the Applicant through documentation review (application forms, self-assessments and supporting documentation), and on-site audits.

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2. Assessment Summary

EURACAN

Coordinating Member

Centre Léon Bérard (CLB) 28 Prom. Léa et Napoléon Bullukian, 69008 Lyon (France)

Healthcare Providers

To perform the technical assessment, a stratified and representative sample of Healthcare Providers per Network application has been selected by the European Commission taking into account the size of the Network, the number of HCPs (Hospitals) and its participation in different networks and the Member State representation.

The Network is composed of the following Healthcare Providers:

- Aarhus University Hospital (Denmark) (*)
- Academic Medical Center Amsterdam (Netherlands) (*)
- Antwerp University Hospital (AUH) (Belgium)
- Assistance Publique - Hôpitaux de Paris: Cochin, G. Pompidou, Paris Descartes (France)
- Azienda Ospedaliera Sant'Orsola Malpighi (Italy)
- Azienda Ospedaliera Universitaria "Federico II", Napoli (Italy) (*)
- Azienda Ospedaliera universitaria Careggi, Florence (Italy)
- Azienda Ospedaliera Universitaria Senese (Italy)
- Azienda Ospedaliero Universitaria Città della Salute e della Scienza di Torino (Italy)
- Azienda ULSS9 Treviso (Italy)
- Candiolo Cancer Institute - FPO IRCCS (Italy)
- Centre Hospitalier Universitaire de Liège (Belgium)
- Centre Léon Bérard (CLB) (France) (*) (**)
- Centro di Riferimento Oncologico di Aviano (Italy)
- Centro Hospitalar do Porto (Portugal) (*)
- Centro Hospitalar e Universitario de Coimbra (Portugal)
- Charité Universitätsmedizin Berlin (Germany)
- Complejo Hospitalario regional Virgen Del Rocio (Spain)
- Erasmus MC: University Medical Center Rotterdam (Netherlands)

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- Fondazione IRCCS Istituto nazionale dei tumori (Italy)
- Fondazione IRCCS Istituto Neurologico Carlo Besta (Italy)
- Fundacion de gestio sanitaria de l'hospital de la Santa Creu i Sant Pau (Spain)
- Hammersmith Hospital - Imperial College Healthcare - NHS Foundation Trust (United Kingdom)
- Hôpital Pitié-Salpêtrière (France)
- Hôpital Tenon (France)
- Hospices Civils de Lyon (France)
- Hospital of Lithuanian University of Health Sciences Kauno Klinikos (Lithuania) (*)
- ICO Hospitalet HUB (Spain)
- Institut Curie (France)
- Institut Gustave Roussy (France) (*)
- Institut Jules Bordet (Belgium)
- Institute of Oncology, Ljubljana (Slovenia)
- Instituto Português de Oncologia de Lisboa Francisco Gentil, EPE (Portugal)
- IRCC Institute of Neurological Sciences of Bologna (INSB) - AUS L di Bologna (Italy)
- IRCCS Humanitas Research Hospital, Milan (Italy)
- IRCCS San Martino (Italy)
- Istituti Fisioterapici Ospitaleirri (Italy)
- Istituto Ortopedico Rizzoli (Italy) (*)
- Istituto Scientifico Romagnolo per lo studio e la cura dei tumori (Italy)
- Karolinska University Hospital (Sweden)
- Leiden University Medical Center (Netherlands) (*)
- M. Sklodowska Curie Memorial Cancer Centre and Institute of Oncology (Poland) (*)
- Maastricht University Medical Center+ (Netherlands)
- Mannheim University Medical Centre (UMM) (Germany)
- Masaryk Memorial Cancer Institute (MMCI) (Czech Republic)
- National Institute of Oncology (Hungary)
- Netherlands Cancer Institute - Antoni van Leeuwenhoek (Netherlands)
- Oslo University Hospital (Norway) (*) (**)

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- Ospedale San Raffaele (Italy)
- Oxford University Hospitals - NHS Foundation Trust (United Kingdom)
- Radboud University Nijmegen Medical Centre (Netherlands)
- Royal Free Hospital - NHS Foundation Trust (United Kingdom)
- Royal Marsden Hospital - NHS Foundation Trust (United Kingdom)
- Sheffield Teaching Hospital - NHS Foundation Trust (United Kingdom)
- Stichting VU-VUmc (Netherlands)
- Turku University Hospital, The Hospital District of Southwest Finland (Finland) (*) (**)
- University College London Hospitals - NHS Foundation Trust (United Kingdom)
- University Hospital Essen (Germany)
- University Hospital Marburg (Germany)
- University Hospital Motol (Czech Republic)
- University Hospital Würzburg (Germany)
- University Hospitals Coventry & Warwickshire NHS Trust (UHCW); The ARDEN NET Centre European Neuroendocrine Tumour Society (ENETS) Centre of Excellence (United Kingdom)
- University Medical Center Hamburg-Eppendorf (Germany)
- University Medical Centre Groningen (Netherlands)
- Uppsala University Hospital (Sweden)
- UZ Leuven (Belgium) (*)

(*) Selected for the Document review.

(**) Selected for the On-site Audit.

Assessor Team

The following assessor team completed the technical assessment:

- José Expósito Hernández. Granada Complex Hospital, Granada. (Spain) (*)
- Almudena Martín Cruz. Ministry of Health, Social Services and Equality. (Spain) (**)
- Carmen De Vicente Guilloto. Progress and Health Foundation, Sevilla. (Spain)
- Juan Francisco Martín Rodríguez. Biomedicine Institute of Seville (IBIS), Sevilla. (Spain)
- Paul Coppo. Assistance Publique - Hôpitaux de Paris. (France)
- Pavel Vítek. Proton Therapy Center Czech, Prague. (Czech Republic)

(*) Team Leader.

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(**) Assessment Coordinator.

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3. Results Overview

3. 1. Assessor's Commentary

Successes

- Relationships and involvement with other Networks already exist within the area of expertise, and makes this proposal a strong one. The Network has a clear identification of the objectives for the next 5 years.
- The thematic group and the different domains identified by the Network are well explained and consistent and the patients will benefit from the expertise within the Network. EURACAN will be enhanced by the existing relationships with other Networks within the area of expertise.
- The Network presents a strong and solid outline and governance procedures (evidence 14) that give consistency and confidence in its future development and capacity for achieving the identified goals.
- Promotion of the safe use of highly specialised diagnostic techniques and services, and the application of recognised international quality standards, certification, and accreditation schemes gives an added value to the EURACAN Network.
- The Network has a very strong multidisciplinary approach, which is a key issue within the Network's area of expertise.
- The Network has a strong action plan to identify educational / training needs, to develop and provide learning tools for professionals within and outside the Network, for patients and for their families.
- The Network collaborates closely with national and international organisations and maintains strong relationships with patient organisations and other European Reference Networks within the area of expertise. This collaboration will improve the exchange and dissemination of expertise, and the development of guidelines and protocols will have benefits from this collaboration.

Challenges

- The presented strategic plan must be considered as the initial one. As this is a very complex Network, it will be enhanced by a more detailed plan in the near future.
- So as to hear patients' voice and to incorporate the opinion of patients and families, the Network has to make an effort to unify and standardise different existing mechanisms in the different Healthcare Providers within the Network.
- An effort to implement a website during its first year of development should be made, as the Network is a source of information in rare or low prevalence and complex diseases for patients and families.
- To facilitate cross-border healthcare, the Network should clearly establish patient pathways and connect with patients' healthcare centres in their country of origin. In addition, the Network should implement guidelines and / or protocols to support transition and continuity of care from childhood to adulthood, in collaboration with its members, affiliated partners and patient organisations.
- The Network has to work on defining the procedures and pathways to manage cross-border patients, as well as the procedures to monitor the adherence to clinical practice guides in the Healthcare Providers within the Network. An effort should be made to define the process to support transition and continuity of care from childhood to adulthood.
- The Network has a formal procedure for the selection or development and dissemination of clinical guidelines, which must be implemented for each domain.

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Recommendations

- Regarding the Good Practice, Outcome Measures and Quality Control theme, further efforts should be made to facilitate electronic support to the Healthcare Providers in order to ensure the access to the necessary patients' clinical data for diagnosis and follow-up, as well as to outcome data and other quality indicators.
- The Network shows a very high grade of expertise and promotes good quality and safe patient care for the rare or complex condition. However, further efforts should be made to establish clear patient pathways based on patient needs, clinical evidence and the best use of resources.
- The Network has a clear governance and coordination structure that includes mechanisms to support monitoring and evaluation, and a relevant patient-centred orientation. However, the Board has to unify the existing mechanisms in the different Healthcare Providers within the Network, so as to hear patients' voice and to incorporate the opinion of patients and families.
- In regards to the Patient Care theme, the Board should ensure a careful commitment and dissemination of clinical guidelines as the best way to improve the quality and delivery of care within the area of expertise. In addition, a data source to monitor the clinical outcomes of EURACAN should be provided.

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3. 2. Overall Compliance with the Operational Criteria

Based on the assessment of compliance against the Operational Criteria for Networks, the following graph represents the overall distribution of the ratings for the Network. Please, see Appendix A for more information on the rating scale used by the assessors.

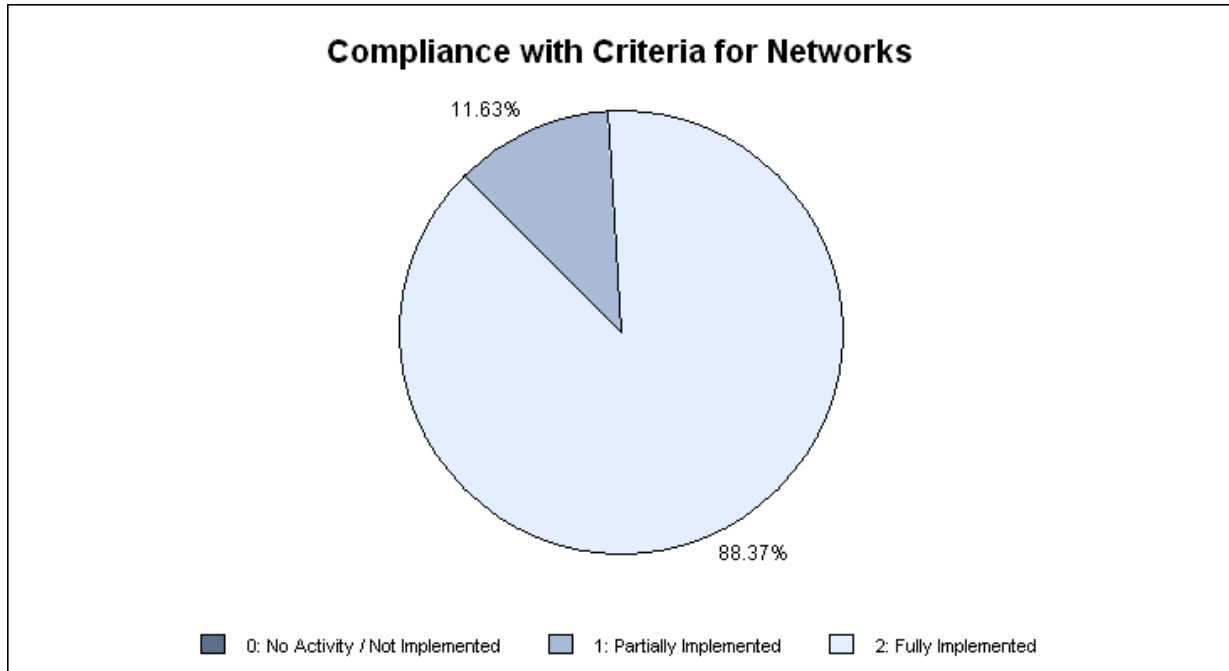


Chart 1

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Compliance was also assessed for the selected Healthcare Provider in the Network against the Operational Criteria for Healthcare Providers. The following graph represents the distribution of the assessor ratings against the criteria for the assessed Healthcare Provider.

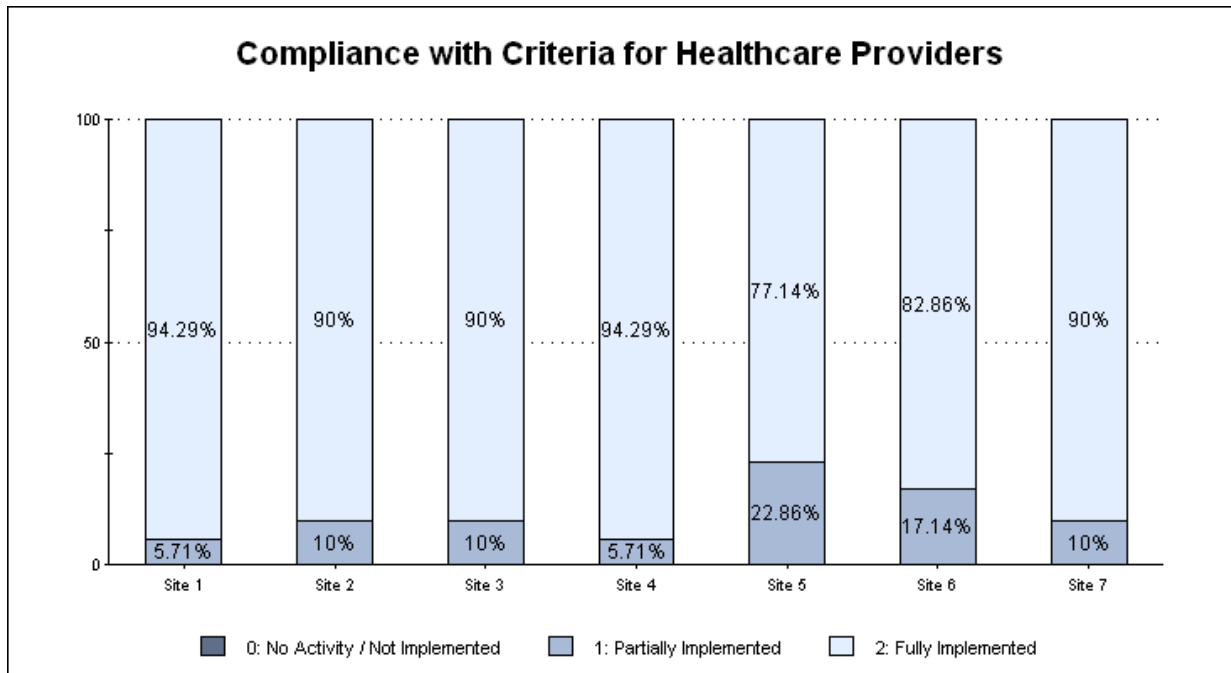


Chart 2

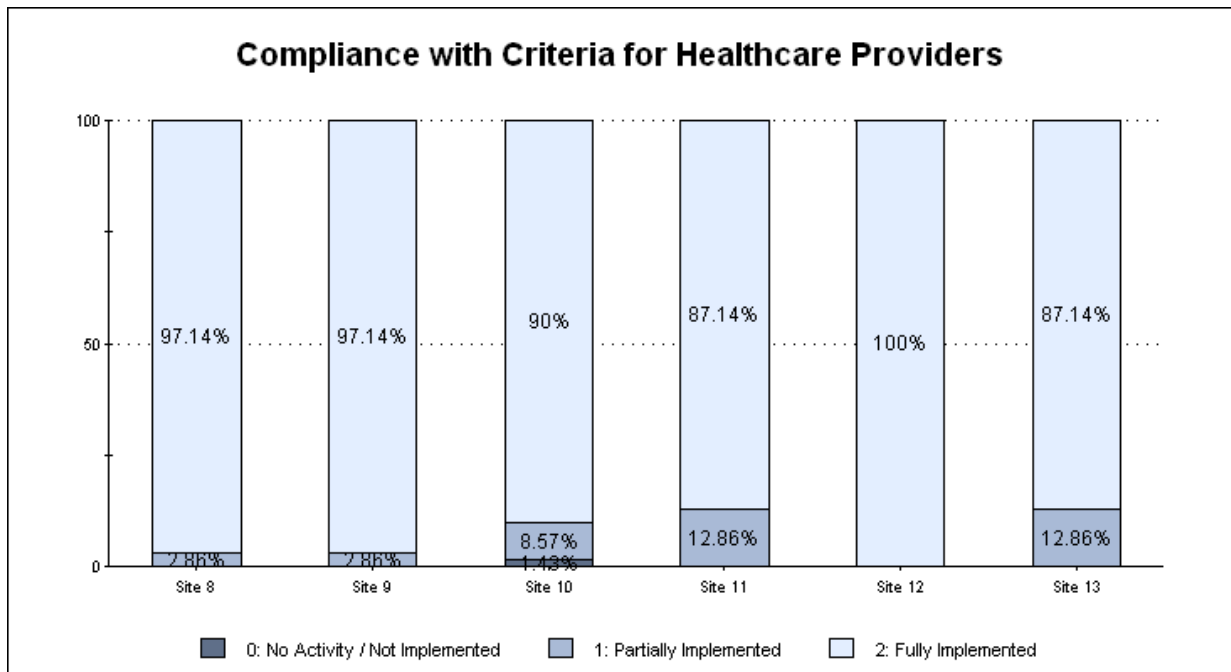


Chart 2

Information about the electronic signature of the document

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Sites	Healthcare Provider
1	Aarhus University Hospital
2	Academic Medical Center Amsterdam
3	Azienda Ospedaliera Universitaria "Federico II", Napoli
4	Centre Léon Bérard (CLB)
5	Centro Hospitalar do Porto
6	Hospital of Lithuanian University of Health Sciences Kauno Klinikos
7	Institut Gustave Roussy
8	Istituto Ortopedico Rizzoli
9	Leiden University Medical Center
10	M. Sklodowska Curie Memorial Cancer Centre and Institute of Oncology
11	Oslo University Hospital
12	Turku University Hospital, The Hospital District of Southwest Finland
13	UZ Leuven

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3. 3. Overview by Themes

Network Results

The Operational Criteria for the Network are grouped into the following 9 themes:

1. Establishment of a European Reference Network
2. Highly Specialised Healthcare
3. Governance and Coordination
4. Patient Care
5. Multidisciplinary Approach
6. Good Practice, Outcome Measures and Quality Control
7. Contribution to Research
8. Continuous Education, Training and Development
9. Networking and Collaboration

Each theme consists of one or more criteria with measures in line with the Commission Delegated Decision (2014/286/EU). The following graph represents the Network average rating for each theme.

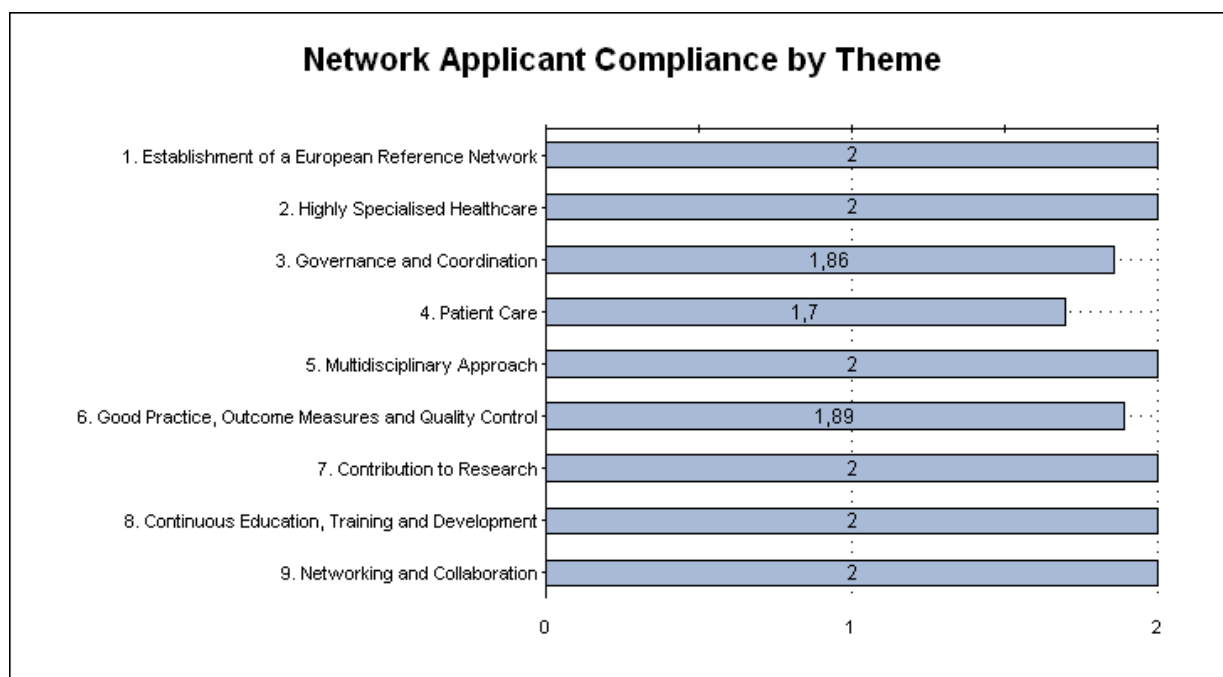


Chart 3

Legend
0: No Activity / Not Implemented
1: Partially Implemented
2: Fully Implemented

Table 2

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The following tables show the Network compliance with the measures in each theme. Based on the assessors' findings, successes and challenges are also highlighted.

Establishment of a European Reference Network	Assessor Rating
1.1.1 The Network is comprised of a minimum of 10 Members across 8 Member States.	2
Average Rating	2

Highly Specialised Healthcare	Assessor Rating
2.1.1 The thematic group(s) and disease(s) or condition(s) within the Network's scope are defined and documented.	2
2.1.2 The Network's area of expertise is highly specialised and well defined and the expected gains of centralising care for these patients can be demonstrated.	2
2.1.3 The objectives of the Network and its activities are clearly defined within a mission and/or vision statement and strategic plan.	2
Average Rating	2

Governance and Coordination	Assessor Rating
3.1.1 There is one designated representative for each applicant member of the Network.	2
3.1.2 The Network is governed by a Board composed of one representative from each Member in the European Reference Network.	2
3.1.3 The role and responsibilities of the Board are clearly defined and documented in a set of governance policies or rules of procedure.	2
3.1.4 The Board monitors the activity, outcomes, and initiatives of the Network and its Members in regards to their specific, predefined role.	2
3.1.5 The Board has established mechanisms to hear from and incorporate the voice and opinion of patients and families.	1
<i>Comments:</i>	
The measures to hear from the patient and/or family do not have the same level of implementation in all Healthcare Providers and the Network has a timeframe of 9 months to work on this issue.	
3.1.6 The Network has a defined strategy for integrating new Members approved by the ERN Board of Member States and Affiliated Partners designated by the Competent National Authorities.	2
3.1.7 There is one Member within the Network designated as the Coordinating Member. One person is appointed by the Coordinating Member to act as the "Coordinator" of the Network.	2
Average Rating	1.86

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Patient Care

Assessor
Rating

4.1.1 The Network works with its Members to establish clear patient pathways based on the needs of patients, clinical evidence, and best use of resources.	1
<i>Comments:</i>	
There is a plan with a clear timeline designed to establish patient pathways in collaboration with the members of EURACAN Network, that is not already in place.	
4.1.2 The Network promotes and/or facilitates the use of information and communication technology (ICT) tools to provide care to patients and share pertinent data within its area of expertise.	2
4.1.3 The Network facilitates the transfer of knowledge on safe, evidence-based, effective and innovative medicine.	2
4.1.4 The Network promotes the safe use of highly specialized diagnostic techniques and services and the application of recognized international quality standards, certification, and accreditation schemes.	2
4.1.5 The Network implements guidelines and/or protocols to support transition and continuity of care from childhood, through adolescence, and into adulthood, where applicable.	1
<i>Comments:</i>	
The process to support transition and continuity of care from childhood to adulthood is not yet resolved. The Network is actively working in these fields within its area of expertise.	
4.2.1 The Network acts as a source of information for rare or low prevalence and complex diseases for patients and families.	2
4.2.2 The Network collaborates with patient associations to improve the safety and quality of care.	2
4.2.3 The Network disseminates information on patient safety standards and safety measures to patients and families to reduce or prevent errors.	2
4.2.4 The Network provides accessible means for patients and families to report possible safety incidents or adverse events and express their views about the care received and their experience, including safety concerns.	2
4.2.5 The Network collaborates with its Members to establish a standardised common tool for measuring patient experience.	1
<i>Comments:</i>	
As stated by the Network, they have defined a plan that will be implemented during the first 18th month of functioning of the Network to establish a common and standardize tool for measuring patient experience.	
Average Rating	1.7

Multidisciplinary Approach

Assessor
Rating

5.1.1 The Network identifies and shares best practices for providing multidisciplinary care.	2
5.1.2 Patient care is delivered across the Network using multidisciplinary healthcare teams.	2
5.1.3 The Network has a process for offering advice for complex patient cases provided by multidisciplinary healthcare teams.	2
Average Rating	2

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Good Practice, Outcome Measures and Quality Control

**Assessor
Rating**

6.1.1 The Network gathers, exchanges, and disseminates knowledge, best practice evidence, and clinical expertise within and outside of the Network.	1
<i>Comments:</i>	
EURACAN aims to improve patient management, and hence must have an open door for all Healthcare Providers which may be in charge of rare cancer patients. Knowledge and informations, in all dimensions will be made available on the EURACAN website.	
6.1.2 Representatives from each Member meet periodically to review and share best practices, and discuss new evidence-based treatments, therapies, and health care technologies.	2
6.2.1 The Network shares expertise and supports healthcare providers in order to bring local, regional and national provision of care to patients closer to home.	2
6.3.1 The Network has a formal process for developing or selecting and disseminating clinical guidelines.	2
6.3.2 The Network adheres to ethical criteria, is transparent, and avoids any conflict of interest when developing and implementing clinical guidelines, patient pathways, and other clinical decision making tools.	2
6.3.3 The Network develops cross border pathways in collaboration with its Members.	2
6.3.4 The Network monitors implementation of established clinical guidelines and patient pathways to encourage consistent use across its Members and monitor their appropriateness. Information is used to make ongoing quality improvements.	2
6.4.1 The Network develops and regularly monitors performance and outcome indicators. The information is used to support ongoing quality improvement.	2
6.4.2 The Network develops and maintains a quality, patient safety, and evaluation framework.	2
Average Rating	1.89

Contribution to Research

**Assessor
Rating**

7.1.1 The Network identifies where there are research gaps and carries out activities to fulfil these gaps.	2
7.1.2 The Network promotes and supports collaborative research amongst its Members, Affiliated Partners, and relevant patient, professional and research organisations.	2
7.1.3 The Network keeps its Members, partners, and patient organizations informed about new research projects and clinical trials.	2
7.1.4 The Network supports at all appropriate levels, including the community level, the establishment of specific disease or condition information networks, shared registries, and databases.	2
Average Rating	2

Continuous Education, Training and Development

**Assessor
Rating**

8.1.1 The Members work together to identify and fulfil education, training, and professional development gaps within the Network’s area of expertise.	2
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8.1.2 The Network facilitates and supports the development and use of standardized continuous education training programmes and tools for healthcare providers within and outside the Network.	2
8.1.3 The Network, in collaboration with partners, provides education and training to healthcare professionals, allied health professionals, and non-healthcare professionals within its area of expertise.	2
Average Rating	2

Networking and Collaboration	Assessor Rating
9.1.1 The Network exchanges and disseminates knowledge and best practices with other Networks and Centres of Expertise.	2
9.1.2 The Network develops a communication plan and establishes communication tools to support collaboration with other organizations.	2
9.1.3 The Network collaborates with Affiliated Partners, i.e. Associated National Centres, Collaborative National Centres or National Coordination Hubs, chosen by Member States.	2
Average Rating	2

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Healthcare Providers Results

The Operational Criteria for the Healthcare Providers are grouped into the following 9 themes:

General Criteria and Conditions

1. Patient Empowerment and Patient Centred Care
2. Organisation, Management and Business Continuity
3. Research, Education and Training
4. Expertise, Information Systems and e-Health Tools
5. Quality and Safety

Specific Criteria and Conditions

6. Competence, Experience and Outcomes of Care
7. Human Resources
8. Organization of Patient Care
9. Facilities and Equipment

Each theme consists of one or more criteria with measures in line with the Commission Delegated Decision (2014/286/EU). The following graph represents the average rating of all the Healthcare Providers in each theme.

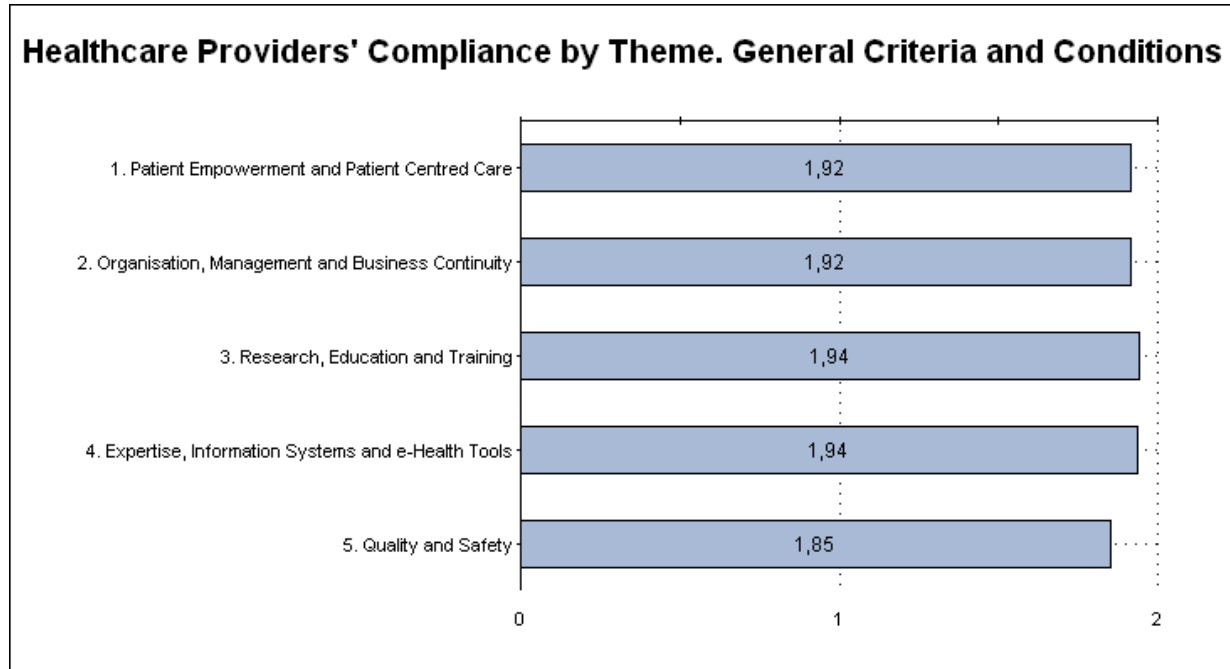


Chart 4

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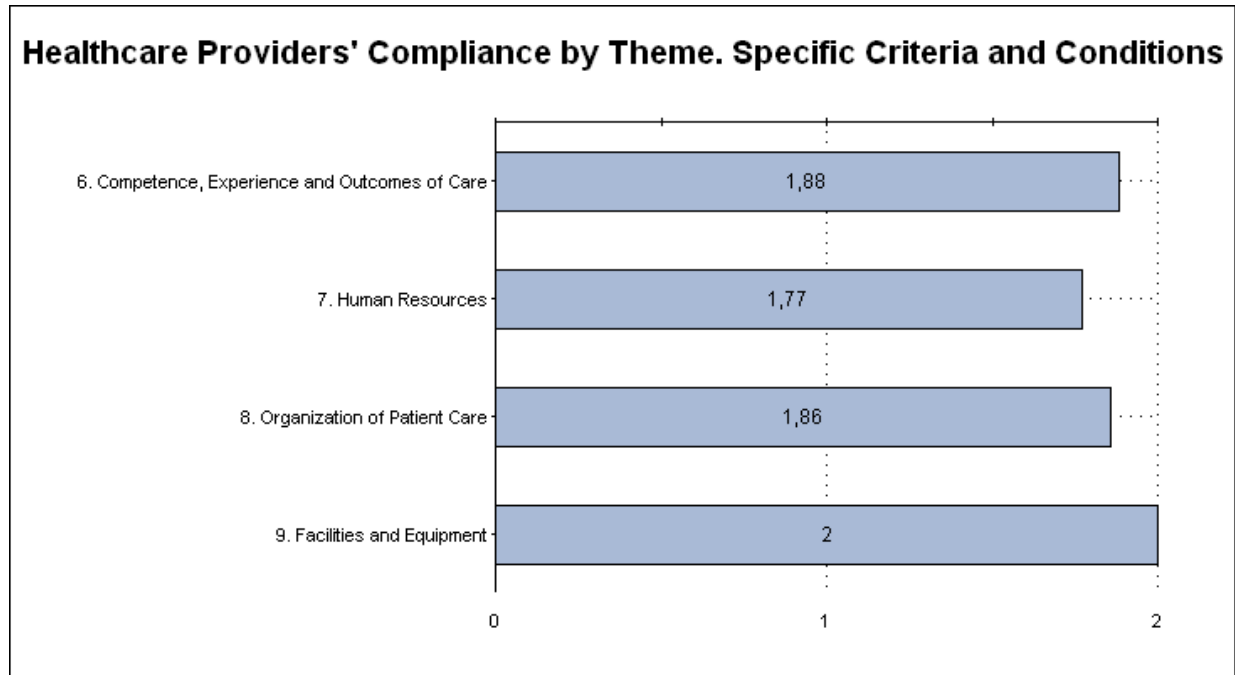


Chart 5

Legend	
0:	No Activity / Not Implemented
1:	Partially Implemented
2:	Fully Implemented

Table 3

Information about the electronic signature of the document

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The following tables show the average rating of all the Healthcare Providers with the measures in each theme.

Patient Empowerment and Patient Centred Care	Assessor Rating
1.1.1 The Healthcare Provider's commitment to patient-centred care is formally and consistently communicated with patients and their families.	2
1.1.2 Processes are in place to assist patients and their families in knowing who is providing their care, and the role of each person on the multidisciplinary care team.	1.92
1.1.3 Patient education materials appropriate for readers of varying literacy levels and for speakers of different native languages are available.	1.85
1.1.4 The Healthcare Provider provides patients and their families with written information about the facility, the organization, and its specific area of expertise.	1.92
1.1.5 The Healthcare Provider gives patients and their families written information about their rights and responsibilities.	2
1.1.6 There is a policy and procedure in place to disclose unanticipated outcomes and complications to patients and their families, as appropriate.	1.85
1.2.1 Patients and their families are given information about how to file a complaint, report violations of their rights, and raise concerns about their care and/or safety.	1.92
1.3.1 The Healthcare Provider routinely measures or facilitates the measurement of patient and family experience using a standardised validated questionnaire. This information is periodically reported to all healthcare professionals and managers involved in delivering care, patients and families, and the general public.	1.92
1.4.1 The Healthcare Provider ensures access to medical records and clinical information is in compliance with EU data protection provisions and national implementing measures, in particular, Directive 95/46/EC.	2
1.5.1 If patient personal health information is exchanged, patients are informed of their rights under the applicable data protection rules and informed consent is obtained. The Healthcare Provider has a policy and standard procedure for obtaining informed consent. The Informed consent is documented in the patient's medical record.	1.92
1.6.1 The Healthcare Provider presents patients and their families with reliable information on clinical outcomes in a form that is useful to them.	2
1.6.2 All relevant information must be provided to patients in an anonymized format, including claims data, patient registry data, clinical data, and patient-reported outcomes.	1.69
1.6.3 Every patient is provided with a full description of the available alternatives for tests and treatments, as well as the pros and cons for each, and the potential risks and benefits.	2
1.6.4 The Healthcare Provider disseminates information to patients and their families on patient safety standards and safety measures to reduce or prevent errors.	1.92
1.7.1 The Healthcare Provider ensures disclosure of all financial and non-financial conflicts of interest related to treatment and/or research activities.	1.85
Average Rating	1.92

Organisation, Management and Business Continuity	Assessor Rating
2.1.1 Management and staff and/or clinician roles and responsibilities specific to the area of expertise are clearly defined in an organization chart.	1.85

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2.1.2 The Healthcare Provider establishes and maintains a set of policies and procedures addressing aspects of management and activities or services within the Network's area of expertise.	1.85
2.1.3 There are policies and procedures for managing cross border patients within the Network's area of expertise.	1.85
2.2.1 The Healthcare Provider provides patients and their families with easy access to information regarding any tariffs that may be in place, services, and benefits.	2
2.3.1 The plan includes the provision of essential medical care in the case of unexpected resource failure, or referral to alternative resources, if necessary; and maintaining stability, technical capacity and expertise of the provider, such as a plan for human resources and updating technology.	2
2.4.1 There are procedures for emergencies and patients presenting outside normal working hours. Patients within the Network's area of expertise can be admitted without delay to a suitable hospital ward service area, where necessary.	2
2.4.2 When necessary, the Healthcare Provider has easy access to other centres or highly specialised units outside its own facilities necessary for diagnosis, treatment, and delivery of care to patients.	1.92
2.5.1 Treatment of patients takes place in dedicated clinical areas that are easily accessible, clean, comfortable, quiet and appropriately equipped.	1.92
2.6.1 The Healthcare Provider provides local clinicians with complete discharge summaries post discharge for all patients.	2
2.6.2 Where possible, the Healthcare Provider uses information and communication technologies, such as eHealth tools, telemedicine/tele-expertise, and case management tools to follow-up post discharge.	1.77
Average Rating	1.92

Research, Education and Training	Assessor Rating
3.1.1 The Healthcare Provider delivers university, post-graduate, or specialised level of education and training in the Network's area of expertise.	2
3.1.2 The Healthcare Provider has a defined set of objectives for its education and training activities.	2
3.1.3 The Healthcare Provider provides evidence that resources are available, i.e. human, technical, or physical structure, to support education and training activities.	2
3.1.4 Education and training activities are delivered to providers involved in the same chain of care within and outside the Healthcare Provider facility.	1.77
3.1.5 The Healthcare Provider evaluates the effectiveness of its education and training activities on an annual basis.	1.92
3.2.1 The Healthcare Provider provides evidence that adequate resources are available, i.e. human, technical, or physical structure, to support research activities.	2
3.2.2 The Healthcare Provider leads and/or participates in research activities and clinical trials, at both a national and international level, within the Network's area of expertise.	2
3.2.3 The Healthcare Provider follows a set of Standard Operating Procedures (SOPs) that govern research activities.	1.92
3.2.4 There is a procedure to review the ethical implications of research activities.	2
3.2.5 The Healthcare Provider maintains and manages records of research activities and clinical trials in accordance with institutional policies and set laws and regulations.	1.92
3.2.6 The Healthcare Provider shares the results of its research activities and clinical trials through scientific publications. The results should be disseminated to other centres and professional and patient associations.	1.85

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3.2.7 The Healthcare Provider evaluates the effectiveness of research activities. 1.92

Average Rating	1.94
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Expertise, Information Systems and e-Health Tools

**Assessor
Rating**

4.1.1 The Healthcare Provider offers an advisory service to exchange expertise with other professionals and caregivers involved in the patients' treatment. 1.92

4.1.2 The Healthcare Provider maintains an accurate database of patients under its care within the Network's area of expertise. 2

4.2.1 The Healthcare Provider follows established procedures to manage, safeguard, and exchange medical data. These procedures are in accordance with the EU data protection legislation, in particular, with Directive 95/46/EC and with Article 2 (e) of the Delegated Decision 2014/286/EU. 2

4.3.1 To support the use of telemedicine and other e-health tools, the Healthcare Provider fulfils the minimum interoperability requirements and when possible, uses agreed to standards and recommendations. 1.92

4.4.1 The Healthcare Provider uses a standardised information and coding system for rare or low prevalence complex disease(s) or conditions(s). 1.85

4.4.2 The Healthcare Provider has procedures in place to monitor and maintain data quality. 1.92

Average Rating	1.94
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Quality and Safety

**Assessor
Rating**

5.1.1 The Healthcare Provider has a quality assurance or management system in place that includes processes to regularly monitor the quality of its performance within the Network's area of expertise. The information it collects is used to make ongoing quality improvements. 1.85

5.1.2 The Healthcare Provider regularly collects and monitors process and outcome indicators. 1.92

5.1.3 The Healthcare Provider has a patient safety programme or plan in place adapted to the Network's area of expertise. 1.77

5.1.4 There is a procedure in place to report, document, investigate, and learn from adverse events and complications. The Healthcare Provider uses this information to make ongoing improvements. 2

5.1.5 The Healthcare Provider contributes performance and outcome data to evaluate the Network, as a whole. 1.62

5.2.1 There is a process to periodically review and share best practices, review the results of clinical audits, review new evidence-based treatments and therapies, and discuss difficult cases. 2

5.3.1 The Healthcare Provider collaborates with other members of the Network or centres of expertise to develop and/or select clinical practice guidelines following a standard evidence-based procedure. 1.85

5.3.2 The Healthcare Provider implements, where possible, clinical practice guidelines agreed to or developed by the Network. 1.69

5.3.3 Clinical practice guidelines are regularly reviewed to ensure they reflect current research and best practice information. 2

Average Rating	1.85
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Competence, Experience and Outcomes of Care	Assessor Rating
6.1.1 The Healthcare Provider regularly monitors and documents its patient activity specific to the Network's area of expertise, disease or condition.	1.85
6.1.2 To maintain its competency and expertise, the Healthcare Provider serves the minimum/optimal number of patients and/or procedures per year as defined by the Network based on professional/technical standards or recommendations.	2
6.2.1 There is evidence that the treatments and advice offered are recognized by international medical science in terms of safety, value, and/or potential positive clinical outcome.	2
6.2.2 The Healthcare Provider shows evidence of good clinical care and outcomes according to available standards, indicators, and knowledge as defined by the Network.	1.69
Average Rating	1.88

Human Resources	Assessor Rating
7.1.1 The Healthcare Provider identifies and documents the skills and professional qualifications required for the staff performing activities critical to the quality of patient care.	1.92
7.1.2 There is a sufficient number of staff with the necessary qualifications to perform the specialized function.	1.69
7.1.3 Each core team member should undertake a minimum number of procedures and/or care for a minimum number of patients in a given year as defined by the Network. The multidisciplinary team should discuss a minimum number of patients per year.	1.85
7.1.4 The Healthcare Provider retains records of staff training, professional development, and maintenance of competencies. There is a process to routinely assess staff skill to ensure adequate performance of specialized tasks.	1.62
Average Rating	1.77

Organization of Patient Care	Assessor Rating
8.1.1 The Healthcare Provider documents the characteristics of the multidisciplinary team.	1.92
8.1.2 There is a designated leader and chair of the multidisciplinary team.	2
8.1.3 There are documented procedures to support the organisation and functioning of the multidisciplinary care team.	1.69
8.1.4 There are regular structured meetings between multidisciplinary team members.	2
8.1.5 Patients receive a periodic clinical or multidisciplinary review. The timeframe is defined based on the area of expertise, disease or condition; and its severity.	1.77
8.1.6 The multidisciplinary team evaluates its performance on an annual basis.	1.77
Average Rating	1.86

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Facilities and Equipment

Assessor
Rating

9.1.1 The Healthcare Provider has available within the centre or easy access to the necessary equipment and facilities to provide good quality patient care.	2
9.1.2 There is access to a specialised laboratory service capable of carrying out all tests required to diagnose the rare or low prevalence complex disease(s) or condition(s) as defined by the Network.	2
9.1.3 There is access to a range of diagnostic technologies as appropriate to the rare or low prevalence complex disease(s) or condition(s) as defined by the Network.	2
9.1.4 Based on the area of expertise, the Healthcare Provider has the capacity to process, manage, and exchange information and biomedical images, or clinical samples with external providers.	2
Average Rating	2

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4. Final Outcome of the Assessment

Scoring Table			
Establishment of a European Reference Network			
Total Score out of a Possible 2	2	Percent of Total	100%
Highly Specialised Healthcare			
Total Score out of a Possible 6	6	Percent of Total	100%
Governance and Coordination			
Total Score out of a Possible 14	13	Percent of Total	92.86%
Patient Care			
Total Score out of a Possible 20	17	Percent of Total	85%
Multidisciplinary Approach			
Total Score out of a Possible 6	6	Percent of Total	100%
Good Practice, Outcome Measures and Quality Control			
Total Score out of a Possible 18	17	Percent of Total	94.44%
Contribution to Research			
Total Score out of a Possible 8	8	Percent of Total	100%
Continuous Education, Training and Development			
Total Score out of a Possible 6	6	Percent of Total	100%
Networking and Collaboration			
Total Score out of a Possible 6	6	Percent of Total	100%
Overall			
Grand Total out of a Possible 86	81	Percent of Total	94.19%

Table 4

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The following table provides a summary of the assessment outcome for each Healthcare Provider.

Healthcare Provider	Eligibility Checklist	Document Review	On-site Audit
1. Aarhus University Hospital	Eligible	Positive Assessment	
2. Academic Medical Center Amsterdam	Eligible	Positive Assessment	
3. Antwerp University Hospital (AUH)	Eligible		
4. Assistance Publique - Hôpitaux de Paris: Cochin, G. Pompidou, Paris Descartes	Eligible		
5. Azienda Ospedaliera Sant'Orsola Malpighi	Eligible		
6. Azienda Ospedaliera Universitaria "Federico II", Napoli	Eligible	Negative Assessment	
7. Azienda Ospedaliera universitaria Careggi, Florence	Eligible		
8. Azienda Ospedaliera Universitaria Senese	Eligible		
9. Azienda Ospedaliero Universitaria Città della Salute e della Scienza di Torino	Eligible		
10. Azienda ULSS9 Treviso	Eligible		
11. Candiolo Cancer Institute - FPO IRCCS	Eligible		
12. Centre Hospitalier Universitaire de Liège	Eligible		
13. Centre Léon Bérard (CLB)	Eligible	Positive Assessment	Positive Assessment
14. Centro di Riferimento Oncologico di Aviano	Eligible		
15. Centro Hospitalar do Porto	Eligible	Negative Assessment	
16. Centro Hospitalar e Universitario de Coimbra	Eligible		
17. Charité Universitätsmedizin Berlin	Eligible		
18. Complejo Hospitalario regional Virgen Del Rocio	Eligible		
19. Erasmus MC: University Medical Center Rotterdam	Eligible		
20. Fondazione IRCCS Istituto nazionale dei tumori	Eligible		
21. Fondazione IRCCS Istituto Neurologico Carlo Besta	Eligible		
22. Fundacion de gestio sanitaria de l'hospital de la Santa Creu i Sant Pau	Eligible		
23. Hammersmith Hospital - Imperial College Healthcare - NHS Foundation Trust	Eligible		
24. Hôpital Pitié-Salpêtrière	Eligible		
25. Hôpital Tenon	Eligible		
26. Hospices Civils de Lyon	Eligible		
27. Hospital of Lithuanian University of Health Sciences Kauno Klinikos	Eligible	Positive Assessment	
28. ICO Hospitalet HUB	Eligible		
29. Institut Curie	Eligible		
30. Institut Gustave Roussy	Eligible	Positive Assessment	
31. Institut Jules Bordet	Eligible		

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32. Institute of Oncology, Ljubljana	Eligible		
33. Instituto Português de Oncologia de Lisboa Francisco Gentil, EPE	Eligible		
34. IRCC Institute of Neurological Sciences of Bologna (INSB) - AUS L di Bologna	Eligible		
35. IRCCS Humanitas Research Hospital, Milan	Eligible		
36. IRCCS San Martino	Eligible		
37. Istituti Fisioterapici Ospitaleirri	Eligible		
38. Istituto Ortopedico Rizzoli	Eligible	Positive Assessment	
39. Istituto Scientifico Romagnolo per lo studio e la cura dei tumori	Eligible		
40. Karolinska University Hospital	Eligible		
41. Leiden University Medical Center	Eligible	Positive Assessment	
42. M. Sklodowska Curie Memorial Cancer Centre and Institute of Oncology	Eligible	Negative Assessment	
43. Maastricht University Medical Center+	Eligible		
44. Mannheim University Medical Centre (UMM)	Eligible		
45. Masaryk Memorial Cancer Institute (MMCI)	Eligible		
46. National Institute of Oncology	Eligible		
47. Netherlands Cancer Institute - Antoni van Leeuwenhoek	Eligible		
48. Oslo University Hospital	Eligible	Positive Assessment	Positive Assessment
49. Ospedale San Raffaele	Eligible		
50. Oxford University Hospitals - NHS Foundation Trust	Eligible		
51. Radboud University Nijmegen Medical Centre	Eligible		
52. Royal Free Hospital - NHS Foundation Trust	Eligible		
53. Royal Marsden Hospital - NHS Foundation Trust	Eligible		
54. Sheffield Teaching Hospital - NHS Foundation Trust	Eligible		
55. Stichting VU-VUmc	Eligible		
56. Turku University Hospital, The Hospital District of Southwest Finland	Eligible	Positive Assessment	Positive Assessment
57. University College London Hospitals - NHS Foundation Trust	Eligible		
58. University Hospital Essen	Eligible		
59. University Hospital Marburg	Eligible		
60. University Hospital Motol	Eligible		
61. University Hospital Würzburg	Eligible		
62. University Hospitals Coventry & Warwickshire NHS Trust (UHCW); The ARDEN NET Centre European Neuroendocrine Tumour Society (ENETS) Centre of Excellence	Eligible		
63. University Medical Center Hamburg-Eppendorf	Eligible		

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64. University Medical Centre Groningen	Eligible		
65. Uppsala University Hospital	Eligible		
66. UZ Leuven	Eligible	Negative Assessment	

Table 5

Decision guideline	
✓	An overall compliance rate of 50% of the maximum score.
✓	There should be no measurement elements under any theme rated as 0.
✓	A minimum of 10 HCP from 8 Member States in a Network must receive a positive assessment against the Healthcare Provider Decision Guidelines.
✓	A rating of 1 for any given measurement element may be accepted provided there is a clear action plan, defined accountabilities, and timeline in place.

Table 6

Based on the overall score and detailed findings in this report, the Network has achieved a:

- Ⓑ **POSITIVE ASSESSMENT**
- Ⓔ **NEGATIVE ASSESSMENT**

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5. Next Steps

The Network and Healthcare Providers are encouraged to follow-up on the recommendations in this report, as appropriate. The following is a summary of the next steps:

- Review the assessment report and notify ACSA about any requests for amendments
- The Board of Member States will issue the final approval for ERNs based on the assessment results

If you have any questions, please contact ACSA through the Communication Area of the project in ERN - Assessment Tool.

Declaration

- The findings have been explained to the Network Coordinator and/or Healthcare Provider Representative

Assessors Team Leader: José Expósito Hernández

Assessment Coordinator: Almudena Martín Cruz

15 November 2016

Antonio Torres Olivera

ACSA Director

Víctor Reyes Alcázar

ERNs Project Coordinator

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Appendix A: Rating Scale

The following rating scale is used by the assessors to assess compliance with the operational criteria for Network and Healthcare Providers. The same rating scale is used by the applicant for the self-assessments.

Rating	Guidelines
0: No Activity / Not Implemented	All Criteria: this rating is used when there is no action plan in place or there is insufficient evidence to support compliance. This rating may also be used when the practice is not implemented in any of the Healthcare Providers of the Network (if applicable).
1: Partially Implemented	All Criteria: this rating is used when there is an action plan in place or there is any evidence to support compliance. This rating may also be used when the practice is implemented by some of the Healthcare Providers of the Network (if applicable).
2: Fully Implemented	All Criteria: this rating is used when there is sufficient evidence to support compliance. This rating may also be used when the practice is implemented by all of the Healthcare Providers of the Network (if applicable).

Table 7

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